REMARKS

Claims 1-27 were originally presented for examination. Of those claims, claims 1, 14, 19, 21, 23, 24, 26 and 27 were independent claims. At the time of the last Office Action, all of the claims were rejected as follows:

1. Claims 1, 4, 5, 14 and 19 were rejected as lacking novelty under 35 U.S.C. §102(b) over CURRIE et al. (5,366,454);
2. Claims 26 and 27 were rejected as lacking novelty under 35 U.S.C. §102(e) over ROSENBLUTH et al. (6,015,424);
3. Claims 2, 3, 6, 7, 10-13 and 20 were rejected as obvious over CURRIE et al. in view of EDER et al. (5,980,550);
4. Claim 8 was rejected as obvious under 35 U.S.C. §103(a) over CURRIE et al. and EDER et al., and further in view of ABRAMS et al. (US 2002/0058640);
5. Claim 9 was rejected as obvious under 35 U.S.C. §103(a) over CURRIE et al. and EDER et al. in view of WALLACE et al. (6,602,269);
6. Claims 15-18 were rejected as obvious under 35 U.S.C. §103(a) over SHEPPARD et al. (6,773,429) in view of ENGLESON (6,024,754);
7. Claims 26 and 27 were rejected as obvious under 35 U.S.C. §103(a) over SHEPPARD et al. in view of WALLACE et al.; and
8. Claims 1-7 and 10-25 were rejected as obvious under 35 U.S.C. §103(a) over HAMM et al. (WO 03/092791) in view of ROSENBLUTH et al.

Applicants wish to thank Examiner Aamer Ahmed for the courteous and productive interview with applicants' undersigned counsel at the Patent and Trademark Office on January 26, 2006.

As discussed during the interview, vascular occlusive embolic coils having a thrombogenic agent thereon have been employed in the past to promote clotting in the treatment of vascular aneurysms. Such prior coils with the thrombogenic agent thereon have been coated with a protective coating or barrier of a water soluble agent which dissolves after placement at the aneurysm. The disadvantage of these coils is that there is no control as to when the dissolution of the protective coating begins and the thrombogenic agent is activated because the dissolution is the result of the action of the blood on the coating. Thus, dissolution of the protective coating and exposure of the bioactive agent may commence upon introduction of the coils to the blood vessel and before it is placed at the aneurysm.

The present invention is directed to such embolic coils with a bioactive agent thereon, for example a thrombogenic agent such as polyglycolic acid, upon which an outer barrier or protective coating is coated which is inert to bodily fluid or blood. Thus, dissolution of the barrier will not take place when simply exposed to the bodily fluids. In the present invention, dissolution of the inert protective barrier is accomplished by the introduction of an external fluid agent once the embolic coils have been placed relative to the aneurysm. The external fluid agent is typically introduced through the placement catheter. In the alternative dissolution of the barrier may also be accomplished by heat or lazer after placement.

Prior independent claims 1, 14, 19, 21, 23 and 24 and new independent claim 28 are directed to a vascular occlusive device. Prior independent claims 26 and 27 are directed to a method of treating an aneurysm using the vascular occlusive device.

The Device Claims

Independent device claims 1, 14, 19, 21 and 24 either were previously amended or have been amended herein to set forth that the outer barrier which is substantially inert to bodily fluid exhibits the characteristic that when exposed to an "external fluid agent" it dissolves, exposes the bioactive agent, permits a reaction between the bioactive agent and the bodily fluid or exposes the support member.

Of these claims, only claims 1, 14 and 19 were rejected on CURRIE et al.

CURRIE et al. discloses a medicine dispensing container which has a delivery opening 20 covered with a rupturable film 24 which is ruptured by pizzoelectric members 26a and b energized by electricity to rupture the film to dispense the medicine from the container compartment 16. It was argued in the last Office Action that the film 24 is "melted". However, as pointed out by applicants' undersigned counsel at the interview, no such reference to being "melted" could be found by him in CURRIE et al. Also as pointed out during the interview no dissolving of the film 24 occurs in CURRIE et al., the CURRIE et al. container is not a vascular occlusive device and does not contain embolic coils as in the present invention, and there is absolutely no external fluid agent" whatsoever disclosed or suggested by CURRIE et al. All of these limitations appear in claims 1, 14 and 19 which were rejected under §102 over CURRIE et al.

Independent claims 21 and 24 were also previously rejected upon CURRIE et al. but the rejection was withdrawn when those claims were amended to call for an external

"fluid" agent to expose the bioactive agent to the bodily fluid. Claims 1, 14 and 19 have also been amended herein to set forth the external "fluid" agent. Accordingly, at the close of the interview, it was agreed that all of the claims which are currently rejected over CURRIE et al. should now be allowable as amended, i.e. independent device claims 1, 14 and 19.

As to the §103 rejection of all of the previous device claims 1, 14, 19, 21, 23 and 24 on HAMM et al. in view of ROSENBLUTH et al., HAMM et al. discloses a medicine dispensing stent which comprises a stent support material, a bioactive agent thereon and a protective barrier on the bioactive agent which comprises a polymer with magnetic particles in the barrier. When the magnetic particles are exposed to either an electromagnetic field, MRI or ultrasound, the particles are pulled out of the polymer to create channels in the barrier to permit the exposure of the bioactive agent beneath the polymer to the bodily fluids. Again, HAMM et al. contains no disclosure or suggestion either of an external fluid agent to initiate exposure of the bioactive layer or a device which is an embolic coil as in the present claimed invention.

ROSENBLUTH et al. does disclose an embolic coil together with some sort of external activating fluid. However, the activating fluid simply rigidifies the coil to harden it and does not dissolve any barrier to expose a bioactive agent to the bodily fluids. In the embodiment shown in FIG. 6 of ROSENBLUTH et al. a cool external fluid is introduced to rigidify the coil polymer itself. In the embodiments shown in FIGS. 7-10, a transition fluid material is fed to the coil after placement which simply leaks out of the coil and rigidifies in situ. In the embodiments shown in FIGS. 11-14, an electric current fuses

elements of the coil to rigidify the coil. And in the embodiment shown in FIGS. 15-16, the transition material 84 hardens.

As discussed during the interview, there is absolutely no disclosure or suggestion whatsoever in ROSENBLUTH et al. to dissolve a protective barrier either as in HAMM et al. or in the present claimed invention. And, even when the device of HAMM et al. is modified by the teachings of ROSENBLUTH et al., a device still does not result in which an external fluid agent dissolves a protective barrier as in the invention claimed in applicants' independent device claims 1, 14, 18, 21 and 24. Accordingly, it was agreed at the close of the interview that those claims should be allowable over the combination of HAMM et al. and ROSENBLUTH et al.

Prior independent claim 23 has been amended herein to call for a heat activating agent for exposing the bioactive support member to bodily tissue and new independent claim 28 has been added to set forth a laser activating agent to expose the bioactive support member to bodily tissue. Ample support appears in the original disclosure at page 10 for such heat and laser activation. None of the prior art currently of record discloses or suggests either heat or laser activation for exposing a bioactive support member to bodily tissue.

The Method Claims

Independent method claims 26 and 27 were rejected as lacking novelty under §102 over ROSENBLUTH et al. or as being obvious under §103 over SHEPPARD et al. in view of WALLACE et al.

ROSENBLUTH et al. again discloses nothing more that rigidifying embolic coils and therefore fails to disclose or suggest the provision of a vascular occlusive device

comprising a support member, a bioactive surface on the support member and a barrier which prevents reaction between the bioactive agent and a bodily fluid as set forth in both of the method claims 26 and 27. Accordingly, those claims clearly define over ROSENBLUTH et al. as they stand and without further amendment.

SHEPPARD et al. simply discloses a container with a reservoir 18 which holds a drug and a cap 20 which is an electrode which is electrically energized to corrode to release the drug. The SHEPPARD et al. container is for implantation but not by catheter delivery, and it is not a vascular occlusive device as in the present claimed invention. Indeed it is a quite bulky and complicated electrode container system which would clearly not be capable of placement through a catheter.

WALLACE et al. discloses nothing more than a catheter conduit for discharging a fluid into an aneurysm for the fluid to polymerize there. Thus, the fluid itself in WALLACE et al. is the occlusive agent. Neither WALLACE et al. nor SHEPPARD et al. provides any clue or suggestion as to how one might utilize the catheter conduit of WALLACE et al. for placing the complex container electrode system of SHEPPARD et al. in place and to energize it.

Indeed, even when the teachings of SHEPPARD et al. and WALLACE et al. are combined, no method results in which anything is applied through a catheter to activate a barrier to expose an inert bioactive agent as in the independent method claims 26 and 27.

For the above reasons, it is respectfully submitted that all of the claims remaining in the present application, claims 1-28, are in condition for allowance. Accordingly,

favorable reconsideration and allowance are requested.

Respectfully submitted,

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